

REMARKS

Careful consideration has been given to the Official Action July 28, 2005 and reconsideration of the application as amended is respectfully requested.

Claims 1-3, 5-14, 16-23 and 27-31 are pending in the application.

The claims have been rejected under 35 USC 103 on cited art.

Claims 1 and 27 the independent claims in the application have been amended to clearly establish the fundamental distinctions between the present invention and the cited art. It is respectfully submitted that the amendatory action which has been taken does not raise new issues nor require further detailed consideration and/or search by the Examiner. This will become evident from the discussion which follows subsequently.

The specification has been amended for purposes of clarification. The amendatory action does not introduce any new matter and is clearly supported by the original disclosure and drawings. Notably, the opening of the closed chamber 8a is located at the rear end of the capillary inflow channel as evident in Figs. 1-3.

Briefly stated, the present invention is patentably distinguished from the cited art by the provision of a control for capillary flow in the inflow channel by the provision of a closed chamber at the rear end of the channel opposite the input end of the inflow channel. This is explained in the specification at page 4, lines 23-28 and page 9, lines 14-18.

Next follows an analysis of the invention and its distinction with respect to the cited art.

THE INVENTION:

The essence of the invention is to apply an equilibrium between capillarity and air pressure provided by a closed chamber located at the rear end of the capillary inflow channel, the air pressure serving as a buffer or air spring to provide a force opposing the capillary action of the sample in the inflow channel, thus effectively controlling the flow of the sample along the capillary inflow channel. As defined in Claim 1, because the chamber is a closed space with its bottom end in communication with the rear end of the capillary inflow channel, when a sample is introduced into the inflow channel by capillary action, it will also compress the air along the capillary inflow channel and in the chamber to increase the air pressure along the capillary inflow channel and in the chamber, which in turn, will cause the sample flow to stop at a certain point along the inflow channel and not go beyond the chamber. Therefore, the volume of the sample can be controlled effectively and possible contamination can be avoided.

REJECTION UNDER USC§103(A):

The rejection of the claims by the Examiner is faulty due to the fact that Bhullar discloses a recloseable biosensor where a pull tab 48 of cover 124 is lifted to separate middle portion 46 of the cover 124 from second and third substrates 114, 122 and open sample port 168 to view. The recloseable cover 124 provides a protective covering for sample 168 during storage before use and prior to disposal (Col 10, Lines 38-40), and includes a raised portion 156 which is sized to receive a sink pad 160 therein, which is in general alignment with sample port 168. When in use, liquid sample 133 is dropped and deposited into sample port 168. Once the concentration of the analyte is determined, adhesive 54 is pressed onto third substrate 122 so that cover 124 extends across sample port 168. The sink pad absorbs liquid sample 133 which remains in contact with cover 124 when the cover 124 seals the liquid sample 133 in the sample port 168.

The main difference between the subject invention and Bhullar is that in the Bhullar

patent, although channel 140 is sized to promote capillary flow of liquid sample 133 across tracks 16, 18 (Col 9, Lines 25 and 26), as indicated by the examiner, the liquid sample 133 cannot be introduced into the channel 140 simply by capillary action upon direct contact with the front tip of the capillary inflow channel, as in the subject invention. Instead, since the cover 124 is recloseable, the pull tab 48 of the cover 124 must be lifted by force first, and liquid sample 133 must be dropped (e.g. from a dropper) by gravity into sample port 168. With such configuration, the volume of the liquid sample cannot be controlled effectively, which is likely to cause contamination. The recloseable cover 124 is totally irrelevant to forming a closed chamber at the terminal end of the capillary inflow channel to provide a force against the capillary action of the sample in the inflow channel. Bhullar therefore cannot render the claims of the invention as obvious.

In addition, Bhullar does not teach or suggest that the flow of the sample can be stopped at a certain point along the capillary inflow channel due to air pressure in the closed chamber, since the channel 140 is open to the atmosphere (Col 10, Lines 28-42), and the raised portion 156 cannot provide air pressure against the flow of the sample along the capillary inflow channel, since there is no way that the air in the channel 140 and the raised portion can be compressed by liquid sample 133 when it is dropped. Rather, the raised portion 156, which is disposed at the front tip of the channel 140, is merely used to receive sink pad 160, which in turn, is formed to absorb fluid when cover 124 extends across sample port (Col 9, Lines 50-56 and Col 10, Lines 25-27, and Lines 43 and 44). There is no need in the present invention to provide a sink pad in the chamber since the air pressure in the chamber itself can effectively control the volume of sample in the capillary inflow channel. For persons having ordinary skill in the art, the application of conventional capillary action along a capillary channel used in conjunction with a closed chamber providing air pressure to control the flow of sample along the capillary channel is a rather revolutionary and novel concept in this field and cannot be considered obvious.

Nankai (US 5,120,420) merely suggests a slot with different shapes and configurations and a layer of electrically conductive wires; it, does not teach or suggest that the flow of the sample can be stopped at a certain point along the capillary inflow channel due to air pressure

in the closed chamber, nor does this follow from the combination of Bhullar and Nankai. It is clear that that the subject invention is non-obvious and patentable over Bhullar and the combination of Bhullar and Nankai.

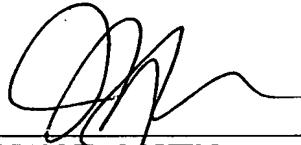
Given the above, it is evident that the subject invention provides a distinctive and unique mechanism with less contamination where the closed chamber serves as an air spring to effectively control the flow of the sample along the capillary inflow channel. Therefore, it appears that the examiner's rejection mainly based on the concept of capillary action and a conventional chamber cannot meet the concept, configuration and operation of the elements defined and described in the claims. Dependent claims 2, 3, 6, 7, 9-14, 16, 19, 20, 22 are also considered patentable over Bhullar. Dependent claims 5 and 21 are considered patentable over Bhullar, Nankai and Lee (US 6,793,802). Dependent claims 8, 17 and 18 are considered patentable over Bhullar and Nankai, and Claim 23 is considered patentable over Bhullar, Nankai and Feldman (US 6,299,757).

Claim 27 recites a method of fabricating an electrochemical biosensor wherein an opening defines a closed chamber within an upper cover above and in communication with one end of a slot formed in the middle layer. The slot defines a capillary inflow channel such that a sample can be rapidly introduced into and fill an electrode layer by capillary upon direct contact with the front tip of the capillary inflow channel, and the flow of the sample is stopped at a certain point along the capillary inflow channel due to air pressure in the closed chamber. Similar to the arguments given in the previous paragraphs, Nankai, Bhullar and Fujiwara (US 6,309,526) and their combination neither suggest nor teach such features. The subject invention provides a revolutionary and unique concept and technical solution which are novel and non-obvious from the prior art, and therefore Claim 27 is also deemed patentable over Nankai, Bhullar and Fujiwara. Similarly, Claim 28 is patentable over Nankai, Claim 29 is patentable over Nankai, Bhullar, Fujiwara and Lee, and Claim 30 is patentable over Nankai, Bhullar and Fujiwara. Claim 31 is patentable over Nankai and Bhullar.

On the basis of the above action and comments, it is therefore respectfully submitted that favourable action and allowance of the claims is fully warranted.

For the record, Applicant would like to note that a Notice of Allowance has been issued in the corresponding Taiwanese application.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'JH Cohen', written over a horizontal line.

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